

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS:	Wood et al.	CONF. NO:	8540
APPLICATION NO.:	10/068,299	GROUP NO:	1651
FILING DATE:	February 6, 2002	EXAMINER:	Barnhart, Lora Elizabeth
TITLE:	CELL SUSPENSION PREPARATION TECHNIQUE AND DEVICE		

Mail Stop Petitions  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PETITION TO WITHDRAW FINALITY UNDER 37 CFR § 1.181**

Pursuant to 37 CFR § 1.181 and MPEP § 1002.02(c), Applicants submit this Petition to Withdraw Finality and request reconsideration of the Advisory Action mailed September 22, 2010 denying Applicants' Request for Withdrawal of Finality filed September 9, 2010. The Commissioner is authorized to charge any fees occasioned by entry of this paper to Attorney's Deposit Account No. 50-2678.

Applicants respectfully request entry of this Petition, in which:

- **Remarks** begin on page 2.
- **Exhibit A:** Amendment and Response filed October 19, 2009
- **Exhibit B:** Non-Final Office Action dated December 30, 2009
- **Exhibit C:** Amendment and Response filed April 29, 2010
- **Exhibit D:** Final Office Action dated July 9, 2010
- **Exhibit E:** Request for Withdrawal of Finality and Amendment and Response filed September 9, 2010
- **Exhibit F:** Advisory Action dated September 22, 2010

### **REMARKS**

MPEP § 706.07(a) specifies the conditions under which the finality of a second or subsequent Office Action is proper, providing that:

“Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information submitted in an information disclosure statement....”

Applicants respectfully submit that the finality of the Final Office Action dated July 9, 2010 is improper under MPEP § 706.07(a), because the Examiner introduced new grounds of rejection that are neither necessitated by Applicants’ amendments nor based on an information disclosure statement. Rather, the Examiner cited a new piece of art to reject a previously presented claim element. As such, the finality is premature and thus, pursuant to MPEP § 706.07(d) withdrawal of the finality is respectfully requested.

In the Final Office Action dated July 9, 2010, the Examiner stated that “[t]he claim amendments require for the first time that the composition contain a population comprising keratinocyte basal cells, melanocytes, and fibroblasts; previously, all that was required was that the cells be viable. The new rejections were necessitated by the amendments to the independent claims.” Final Office Action dated July 9, 2010 at page 6, emphasis added (see Exhibit D). Applicants respectfully disagree. The recitation of keratinocyte basal cells, melanocytes, and fibroblasts was not presented for the first time in the Amendment and Response filed April 29, 2010 (see Exhibit C). Rather, the recitation was presented in the preceding Amendment and Response filed October 19, 2009 (see Exhibit A) and considered by the Examiner as a claim limitation in the Non-Final Office Action dated December 30, 2009 (see Exhibit B).

Specifically, the relevant prosecution history is as follows:

1. In the Amendment and Response filed October 19, 2009, independent claims 19 and 61 recite “a ratio of keratinocyte basal cells, melanocytes, and fibroblasts that is comparable to a ratio of keratinocyte basal cells, fibroblasts and melanocytes present in said tissue sample.”
2. In the Non-Final Office Action dated December 30, 2009, the Examiner requested clarification of “ratio” (see page 4) and rejected the claims alleging

that Noel-Hudson's biopsy contains "all of the cell types recited in claims 29, 61, and 65" (see page 6).

3. In the Amendment and Response filed April 29, 2010, Applicants amended the claims to remove "ratio" and to recite "a cell population comprising keratinocyte basal cells, melanocytes, and fibroblasts, the cell population of the composition and the skin tissue sample being comparable."
4. In the Final Office Action dated July 9, 2010, the Examiner alleged that the claims "require for the first time" keratinocyte basal cells, melanocytes, and fibroblasts (see page 6).

From the above prosecution history, it is clear that the recitation of keratinocyte basal cells, melanocytes, and fibroblasts was previously presented for examination (i.e., in the Amendment and Response filed October 19, 2009) and previously considered by the Examiner as a claim limitation (i.e., in the Non-Final Office Action dated December 30, 2009). Specifically, one of ordinary skill in the art would understand that in the claims dated October 19, 2009, "a ratio of keratinocyte basal cells, fibroblasts and melanocytes present in said tissue sample" necessarily requires the presence of all three cell types, because keratinocyte basal cells, fibroblasts and melanocytes are necessarily present in a dermal-epithelial (i.e., skin) tissue sample. This position is in agreement with the Examiner's finding that skin contains keratinocytes, melanocytes, and fibroblasts. See Non-Final Office Action dated December 30, 2009 at page 6. Thus, the recitation of keratinocyte basal cells, melanocytes, and fibroblasts was previously presented in the Amendment and Response filed October 19, 2009, and cannot be reasonably said to be presented for the first time in the Amendment and Response filed April 29, 2010.

Furthermore, it is clear that in the Non-Final Office Action dated December 30, 2009, the Examiner understood that the claims required at least the three cell types (i.e., keratinocyte basal cells, melanocytes, and fibroblasts). Specifically, the Examiner cited Van Bossuyt to support the position that skin contains keratinocytes, melanocytes, and fibroblasts, and that Noel-Hudson's biopsy contains "all of the cell types recited in claims 29, 61, and 65." See Non-Final Office Action dated December 30, 2009 at page 6. Therefore, the Examiner has previously considered as a claim limitation that the claimed composition includes keratinocyte basal cells, melanocytes,

and fibroblasts (i.e., in the Non-Final Office Action dated December 30, 2009). Thus, this claim limitation cannot be reasonably said to be considered for the first time in the Final Office Action dated July 9, 2010.

Indeed, the Examiner herself stated in the Advisory Action dated September 22, 2010, that the Examiner has previously interpreted the claims as requiring the recited cell types in the Non-Final Office Action dated December 30, 2009: “In the interest of compact prosecution, the examiner granted applicant the courtesy of interpreting the claims favorably for art rejection purposes. (12/30/09 Office action, page 5.)” Advisory Action dated September 22, 2010 at pages 2-3 (see Exhibit F). Whether by courtesy or obligation, the Examiner previously gave consideration to this claim limitation prior to the Final Office Action dated July 9, 2010 and the record clearly reflects it. The Examiner cannot now allege that “[t]he claim amendments require for the first time ... keratinocyte basal cells, melanocytes, and fibroblasts.... The new rejections were necessitated by the amendments to the independent claims.” The improper finality puts the Applicants at a procedural disadvantage, limiting the Applicants’ ability to promote the prosecution of the application by entry of amendments and remarks responsive to the outstanding Office Action.

At least because the recitation of keratinocyte basal cells, melanocytes, and fibroblasts was not presented for the first time and was previously considered by the Examiner, Applicants respectfully submit that the new grounds of rejection introduced in the Final Office Action were neither necessitated by a claim amendment nor an information disclosure statement. As such, the conditions set forth in MPEP § 706.07(a) have not been satisfied. Accordingly, for that reason alone, as well as the interests of fairness, Applicants respectfully submit that the Final Office Action dated July 9, 2010 is premature and request the finality be reconsidered and withdrawn.

**CONCLUSION**

Pursuant to 37 CFR § 1.181 and MPEP § 1002.02(c), Applicants respectfully request reconsideration of the request for withdrawal of finality denied in the Advisory Action dated September 22, 2010. Withdrawal of the finality is also petitioned. The Office of Petitions is welcome to contact Applicants' Attorney at the number below with any questions.

Respectfully submitted,

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